**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re U.S. Patent 6,353,038

Allan AHO et al.

Serial Number: 09/446,630

Issued: March 5, 2002

For: NOVEL PLASTIC BASED COMPOSITE AND ITS USE

# DECLARATION OF DR. JUKKA TUOMINEN

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Jukka TUOMINEN, hereby declare as follows:

## Scientific Training and Employment History

1. I earned a Master of Science in Technology degree from the Helsinki University of Technology, Helsinki, Finland, in 1996. Four years later I was awarded my Licentiate of Technology, and in 2003 I was awarded the degree of Doctor of Science in Technology, again from the Helsinki University of Technology.

2. I was employed by the Helsinki University of Technology in the Laboratory of Polymer Technology from October 1994 to May 2003. I was initially a Research Assistant, and was promoted to Research Scientist in August 1996. During this time I also worked as a consultant to JVS-Polymers Oy (September 1998 to May 2003).

3. From June 2003 to October 2008 I was employed by Controlled Therapeutics (Scotland) Ltd. I was initially a Polymer Scientist, Project Leader, and was responsible

for the start-up of the polymer laboratory activities, including leading the polymer development group and being project leader for new polymer technology. I was promoted to the Head of Polymer Science in July, 2005. My responsibilities included leading research in new polymers for controlled drug delivery, operational leadership in polymer production scale-up and day-to-day operation of the polymer laboratory.

4. I have been employed by Vivoxid Oy, Turku, Finland ("Vivoxid") as Technology Development Director since October 2008. In this capacity I direct Vivoxid's research and development projects, while retaining hands-on research in polymers and polymer composites. I am part of Vivoxid's management team, reporting directly to the CEO.

5. I am a named inventor of U.S. Patent 7,256,250 as well as in several pending patent applications, including published U.S. applications 2011/0091488, 2012/0040002 and 2012/0040015.

6. My curriculum vitae is attached.

Vivoxid's Maintenance Fee Payment System

7. Vivoxid has always had less than 30 employees and currently has 7 employees. No Vivoxid employee was dedicated to only patent matters. Mr. Lucchesi, a Vivoxid employee, was responsible for Vivoxid's intellectual property matters until December 2009.

8. Vivoxid does not maintain an internal docket for maintenance and annuity payments. Instead, Vivoxid contracted with Patrafee Oy AB, a commercial annuity

payment service company, to handle its annuity and maintenance fee payments. On information and belief, Vivoxid's Finnish patent counsel, Turun Patenttitoimisto Oy ("Turun") would inform Patrafee of each new Vivoxid application or patent for which an annuity or maintenance fee would be payable. Patrafee would enter the relevant information into its docketing system, and would periodically send Vivoxid a reminder listing those annuities and maintenance fees which would become due in the next few months. Each of these fees would be paid unless Vivoxid instructed Patrafee not to pay a specific annuity or maintenance fee.

9. On information and belief, Mr. Lucchesi did not receive formal training in annuity payment procedures. However, I regard him as trustworthy and capable of overseeing Patrafee's annuity payment services on Vivoxid's behalf.

10. I assumed responsibility for Vivoxid's intellectual property matters in December 2009, after Mr. Lucchesi transferred to BonAlive Biomaterials, Ltd. As part of my IP responsibilities, I communicated with Patrafee regarding payment of annuity and maintenance fee payments. I also met periodically with Turun to discuss Vivoxid's patent portfolio, including prosecution of pending applications.

11. On information and belief, Vivoxid's patent portfolio comprised more than 15 patent families, with some families having more than 20 pending applications and issued patents, in 2009. Vivoxid employed a shorthand name or reference for each patent family for convenience. Thus, "Sulamuovi" is an internal Vivoxid reference for

a patent family which includes U.S. Patent 6,353,038 ("the '038 patent"). Other Vivoxid shorthand names for its patent families include "Ti-geeli", "Lonkkaprotpinnoitus" and "Iskuluja biohajoava materiaali".

Facts Surrounding Non-Payment of the Second Maintenance Fee

12. On information and belief, Patrafee correctly docketed the maintenance fee payment dates for the '038 patent. Exhibit I is a Patrafee reminder dated March 5, 2009 to Vivoxid which correctly lists the '038 patent, its second maintenance fee due date of 5 September 2009, and Vivoxid's patent family reference "Sulamuovi".

13. Vivoxid decided to abandon 2 patent families ("Ti-geeli" and "Lonkkapropteesipinnoitus") in early 2009. Instructions not to pay annuities for these patent families were communicated by Mr. Lucchesi to Patrafee. See Exhibit 2, which is an e-mail dated March 12, 2009 from Mr. Lucchesi to Peter Holmqvist, a Patrafee employee.

14. On information and belief, the second maintenance fee for the '038 patent was unavoidably delayed due to miscommunication between Mr. Lucchesi and Mr. Holmqvist, and subsequent non-communication between Patrafee and Vivoxid. The miscommunication occurred because Mr. Holmqvist mistakenly used Vivoxid's "Lonkkapropteesipinnoitus" patent family reference in connection with the '038 patent in an e-mail sent to Mr. Lucchesi. See Exhibit 3. Mr. Holmqvist should have used the Vivoxid reference "Sulamuovi" in connection with the '038 patent.

15. On information and belief, Mr Lucchesi failed to notice Mr. Holmqvist's mistake. Instead, Mr. Lucchesi erroneously instructed Mr. Holmqvist the "payment " should be abandoned. See Exhibit 4, which is an e-mail reply dated June 5, 2009 from Mr. Lucchesi to Mr. Holmqvist confirming the September "payment" , i.e, the '038 patent, refers to the patent families which Vivoxid is abandoning, and thus can be canceled, i.e., abandoned, at once. The '038 patent number is not recited.

16. On information and belief, the non-communication occurred because Vivoxid either never received or lost a Vivoxid letter dated which confirmed the '038 patent was to be abandoned. See Exhibit 6, which is a letter dated June 9, 2009 Patrafee mailed to Mr. Lucchesi which confirmed their understanding that the '038 patent was to be permitted to lapse by non-payment of the second maintenance fee.

17. As part of the investigation into the non-payment of the second maintenance fee for the '038 patent, I searched the Vivoxid files, but could not locate the original of Exhibit 6. (Exhibit 6 is a file copy retrieved from Patrafee's files.) On information and belief, Mr. Lucchesi also searched Vivoxid's files as part of this investigation, and also could not locate the original of Exhibit 6. Accordingly, I conclude Vivoxid either never received the original of Exhibit 6 from Patrafee or the original was somehow misplaced.

Date and Manner In Which Vivoxid Became Aware of Expiration of the '038 Patent

18. Vivoxid never intended to abandon the '038 patent.

19. Vivoxid became aware the second maintenance fee for the '038 patent had not been paid on or about March 29, 2012.

20. The circumstances surrounding the discovery of non-payment of the second maintenance fee are as follows:

A. Patrafee sent me an annuity reminder dated March 5, 2012 which lists annuity fees coming due in the next few months on patents and pending applications. See Exhibit 11.

B. On March 28, 2012 I began to review Exhibit 11, and saw that annuity fees for eleven patents belonging to Vivoxid's "Sulamuovi" patent family were becoming due. However, I noticed the corresponding U.S. patent for the "Sulamuovi" patent family (the '038 patent) was not listed.

C. I sent an e-mail to Ms. Kaisa Suominen of Turun requesting the status of the '038 patent on March 28, 2012. Ms. Suominen did not respond that day, so I sent an e-mail to Mr. Kim Roering of Turun requesting the same information on March 29, 2012. Mr. Roering then informed me the '038 patent had expired because its second maintenance fee had not been paid.

D. I immediately asked Mr. Roering to determine whether we could revive the '038 patent, and began an internal investigation into how the '038 patent had expired.

21. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. These statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the '038 patent.

Signed this 4 day of May, 2012.

Dr. Jukka TUOMINEN

Enclosure:
CV of Dr. Jukka TUOMINEN

*CURRICULUM VITAE*

# DR. JUKKA TUOMINEN

## PERSONAL DETAILS

Date of birth: 25/10/69, Porvoo, Finland

## EDUCATION

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|---|---|
| 02/2000 – 03/2003 | **Doctor of Science in Technology**<br>Department of Chemical Technology, Helsinki University of Technology, Finland<br>Title of thesis: Chain linked lactic acid polymers: polymerization and biodegradation studies<br>Majors: Polymer technology, organic chemistry |
| 08/1996 – 02/2000 | **Licentiate of Technology**<br>Department of Chemical Technology, Helsinki University of Technology, Finland.<br>Title of thesis: Polymerization of lactic acid polymers by chain extending technology and the properties thereof<br>Majors: Polymer technology, organic chemistry. |
| 01/1990 – 08/1996 | **Master of Science in Technology (Chem. Eng.)**<br>Department of Chemical Technology, Helsinki University of Technology, Finland.<br>Title of thesis: "Production of lactic acid based poly(ester-urethane) in batch reactors" (in Finnish)<br>Majors: Polymer technology, organic chemistry, industrial chemistry |

## TECHNICAL EXPERTIES

- Development of novel bioresorbale composites for load bearing medical devices including optimization, manufacturing and characterization of glass fiber and composite
- Development and design of novel polymers for female heath care in the field of controlled drug delivery
- Process design and scale-up of biodegradable and biomedical polymers, and monomers: e.g. scale-up of a production process from a small batch process to a RIM process for a marketed pharmaceutical polymer in controlled drug delivery
- Polymer and composite processing: extrusion, injection moulding, melt impregnation, film extrusion, dispersion coating
- Polymerization reaction engineering: REX and RIM
- Optimization of reaction conditions and process conditions for polymers, monomers and composites
- Synthesis and polymerization of thermoplastic and thermoset biopolymers, polyurethanes, hydrogels and monomers
- (Bio)degradation studies in vitro and in vivo
- Drug release studies in vitro
- Crystallization, microparticles, particle analysis and filtration development

- Physical and chemical characterization techniques:
  - Triple detection GPC, NMR, DSC, ATR-FTIR, mechanical testing, DMA, MALDI-TOF, AAS, rheometry, UV-VIS, titrimetric analysis, SEM, GC, HPLC
- Patent, scientific and technical paper writing

## PROFESSIONAL EXPERIENCE

10/2008 – PRESENT **Vivoxid Oy**, Turku, Finland

***Technology Development Director***

- Lead and guide R&D department including FiberLive (2008- present), BonaLive (2008-2010) and MetaLive (2008-2010) technology research & development projects in the field of medical devices
  - FiberLive™ platform: Development of load bearing resorbable glass fiber reinforced composites for trauma, spine and sports medicine markets.
  - BonAlive™ platform: Bioactive glass products as bone substitutes for bone reconstruction and augmentation; development of a new package for BonAlive™ granules including marketing authorization and development of a new BonAlive™ Putty product. Participating in finalization of 10 years clinical study follow-up of BonAlive™ granules for knees, cysts and spine indications.
  - MetAlive™ platform: Soft tissue attachment to metal implants such as hearing aids, stents and dental implants by sol-gel $TiO_2$ surface modification.
- Hands-on working in the field of composites and polymers
  - Formulation development of silanization, sizing, polymerization, extrusion, injection moulding, glass manufacturing, fiber drawing, melt impregnation, pultrusion, filament winding and composites.
  - Optimization of operation parameters for bioresorbale polymers and composites
  - Setting-up of a laboratory. Purchase of analytical & characterization equipment, injection molding & extrusion machines, molds and accessories.
  - Engineering, equipment modification, process development, including clean room working.
  - Characterization method development and analytical services from and test trials with companies and universities in the field.
  - Preclinical study sample manufacturing
- Management team member of Vivoxid, report to CEO, technical presentations to Vivoxid board and meetings with investors and companies in the field, steering group member of multiple TEKES projects (Finnish Funding Agency for Technology and Innovation), complaint evaluation team member.
- Day-to-day responsibility
  - Close working with 10-12 subordinates including 5 project managers (2 technology developments, 1 regulatory, 2 clinical) as direct subordinates.
  - Organize R&D meetings, participate in internal & external audits, project & planning meetings, FMEA, risk assessments, design inputs, outputs and

reviews.

- Appraisals, personal development plans, recruit and interview new R&D members and handling layoffs.
- Close working with production, regulatory, QA, Marketing & Sales.

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7/2005 – 10/2008 **Controlled Therapeutics (Scotland) Ltd.** East Kilbride, UK

***Head of Polymer Science***

- Project leader in "New Polymer Technology for Controlled Drug Delivery" project (directly ~£0.4M/year, 3 scientists; indirectly ~£1M/3 years, 7-9 scientists): Including project planning, hands-on polymerisations (PU, PEG and polyester based) and process development (PU extrusion & injection moulding), raw materials, polymer and product characterisation (triple detection GPC, DSC, DMA, NMR, mechanical testing, FTIR, Maldi-tof, rheology, toxicity studies), data and results interpretation. Test trials with other companies in UK and Germany.
- Co-project/operational leader in "Polymer Production Scale-Up" project (£0.5M/2 years, in-house team 5-7 scientists and 4 consultants): Scale-up 10-20 times the existing PU polymer production. Including feasibility, unit operation selection studies, hands-on polymerisation reaction engineering (extrusion & RIM), polymer characterisation, test trials with other companies in UK and Germany, selection of the process manufacture and analyse of the quotations (2.2 ME) from the manufactures.
- Responsible for day-to-day polymer laboratory activities: three direct subordinates (1PhD, 2 BSc), supervision and hands-on development of crosslinked, thermoplastic and biodegradable polymers for controlled drug release. Design of a new polymer laboratory (~£0.3M ) and purchasing of a reactor and modernise the polymer and characterisation equipment. Technical report and standard operation procedure writing. Data and laboratory book checking. Development and design of PU based RelastomerTM HA & DA polymers for vaginal rings.
- Close working and reporting to R & D director, MD, senior management team and CEO.
- Increasing of intellectual property portfolio and working with intellectual property agency.
- Appraisals for subordinates and occasionally helping HR for interviewing and recruiting new scientists/workers. Supervision of thesis workers (Chem.Eng./MSci, University of Strathclyde, Glasgow, UK) and summer students.
- Travelling ~25%.

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06/2003 – 07/2005 **Controlled Therapeutics (Scotland) Ltd.** East Kilbride, UK

***Polymer Scientist, Project Leader***

- Start-up of polymer laboratory activities, lead the polymer development group and project Leader in "New Polymer Technology" project. Direct reporting to R&D Director.
- Supervision and hands-on development of biostable and biodegradable polymers for controlled release devices such as vaginal rings, hydrogels, microparticles, microgels, pessaries, implants, transdermal patches and diffusion loading, dissolution (UV), diffusion and degradation studies.
- Thermal processing and drug loading of polymers - extrusion, blending, compression moulding, thermoforming and injection moulding.
- Writing technical reports, patent application and standard operation procedures.
- Participating management training, conferences, exhibitions technical courses, MALLS & LALLS-SEC, DSC, DOE, SPC, process analytical technology (PAT) training courses.
- GLP, basic training for GMP, ISO 8 Cleanroom environment working experience.
- Analytical services (GPC, NMR, DSC) from and cooperation with UK Universities and Institutions.

09/1998– 05/2003

**JVS-Polymers Oy**, Espoo, Finland.

***Consultant*** (Part time, min. average 10 hours per week, evenings and weekends)

- Industrial co-operation concerning polymerisation, reactive extrusion, process, coating, package and application development with Fortum Oil and Gas Oy (former Neste Oyj), Raisio Chemicals Ltd., Apac AG (Germany), Leiras Oy (part of the Schering Group).
- Development and design of lactide and lactic acid based POLLAIT® and POLLCOAT™ polymer technology with Fortum Oil and Gas Oy.
- Co-supervisor for research assistants.
- Patent research, literature and feasibility studies of biomedical and biodegradable polymers (copolymers of lactide and caprolactone) and monomers. Co-author for numerous technical reports for Leiras Oy and Fortum Oil and Gas Oy, Evaluation of drug permeation through polyolefins and medical polyurethanes.

8/1996 – 5/2003

**Helsinki University of Technology**, Espoo, Finland

***Research Scientist*** at Laboratory of Polymer Technology

- Cooperation and application studies concerning polymers with industrial partners; Fortum Oil and Gas Oy, M-real Ltd., Raisio Chemicals Ltd., Kemira Oy, VTT, and other Finnish Universities.
  - Pilot-scale extrusion and dispersion coating of paper and cardboard, and injection moulding.
  - Bench- and pilot-scale synthesis (6 and 500kg) and polymerisations (30 and 500kg).
- Reactive extrusion (co-rotating 25mm twin-screw) and development of semi-continuous two-step process for lactic acid based poly(ester-urethane).
- Polymerisation of biodegradable polymers for mass volume and biomedical applications.

- Thermosets: poly(lactic acids), polycaprolactone, copolymers; Thermoplastics: poly(lactic acids), poly(ester-urethanes), poly(ester-amides), polycaprolactone, poly(ortho-esters), and copolymers.
- Laboratory, bench (2 and 6 kg) and pilot-scale (30 and 500 kg) polymerisation of lactic acid and caprolactone based polymers.

- Biodegradation studies in hydrolysis and in biological environment (compost).
- Hands-on characterization of polymers and monomers with NMR, FTIR, SEC/GPC, DSC, DMTA, SEM, HPLC, Instron, Karl Fisher and data interpretation.
- Biomedical applications development.
  - Controlled release of active agents, self-reinforcing, and biodegradable composites.
- Researcher at bio- and nanopolymer research group, which was one of Academy of Finland the centres of excellence 2002-2007.
- Synthesis and purification of 2,2'-bis(2-oxazoline) (0.5kg), L-lactide (6kg and 500kg), bis(ketene acetal) monomers (0.1kg).
- Instructor of master's thesis and supervisor for research assistants.
  - "Utilization of an acetylated anhydroglucose oligomer in different polymerisations", Thomas Gädda, 2002; "Synthesis and characterization of crosslinked biodegradable polyester", Markus Turunen,1999; "Synthesis of poly(ortho ester) II", Juha Tuovinen, 1999.
- Teaching experience at Helsinki University of Technology.
  - Biopolymers (Kem-100.570), spring 2000 and 2002; Special work on Polymer Technology (Kem-100.640); Polymerisation Engineering Exercises (Kem-100.400), fall 1997 and 1998; Preparation and checking of exams (Kem-100.570) for undergraduate and postgraduate.

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10/1994 – 8/1996

**Helsinki University of Technology**, Espoo, Finland

***Research Assistant*** at Laboratory of Polymer Technology

- Bench-scale (6kg) polymerisation and characterization of lactic acid based poly(ester-urethanes).

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05/1994 – 8/1994

**Neste Oy**, Porvoo, Finland

***Operator***

- Suspension polymerisation of PVC in pilot scale (50kg).

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05/1993 – 8/1993

**Neste Oy**, Porvoo, Finland

***Operator***

- Suspension polymerisation of polystyrene in pilot scale (300kg)

**LANGUAGE EXPERIENCE**

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- Finnish (mother tongue)

- English – spoken and written – Excellent (Official Company Language)
- Swedish, German and Spanish – Basics

## OTHER

- Reviewer for Biomacromolecules (ACS Publications).
- Member of The American Chemical Society and Finnish Biomaterial Society.
- Steering board member of Department of Biomedical Engineering, Tampere University of technology.
- Injection Moulding Technology Part 2-Special Course at Bell College, Hamilton, UK, on 16, 17, 22 and 23 March 2005.
- Military service in the Finnish Defence Forces, 1989-1990.
- Exchange student at Jumpertown high school, Booneville, Mississippi, USA 1986-1987.